

Complete Summary

GUIDELINE TITLE

HIV infection.

BIBLIOGRAPHIC SOURCE(S)

Finnish Medical Society Duodecim. HIV infection. In: EBM Guidelines. Evidence-Based Medicine [Internet]. Helsinki, Finland: Wiley Interscience. John Wiley & Sons; 2007 Mar 16 [Various].

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Finnish Medical Society Duodecim. HIV infection. In: EBM Guidelines. Evidence-Based Medicine [Internet]. Helsinki, Finland: Wiley Interscience. John Wiley & Sons; 2006 Mar 24 [Various].

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV) infection

GUIDELINE CATEGORY

Counseling
Diagnosis
Management
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Health Care Providers
Physicians

GUIDELINE OBJECTIVE(S)

Evidence-Based Medicine Guidelines collect, summarize, and update the core clinical knowledge essential in general practice. The guidelines also describe the scientific evidence underlying the given recommendations.

TARGET POPULATION

Patients with suspected or known human immunodeficiency virus (HIV) infection

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Assessment of clinical signs and symptoms
2. HIV testing with patient consent, including screening of pregnant women:
 - HIV antibody test
 - HIV nucleic acid test

Counseling/Management/Prevention/Treatment

1. Patient education and counseling
2. Referral to specialist care for disease staging, treatment, and prognosis
3. Notification of patient contacts
4. Hepatitis testing and vaccination as indicated (if patient is intravenous drug user, commence hepatitis B vaccination programme)
5. Medication management with highly active antiretroviral therapy (HAART)
6. General medical care of HIV-infected patients
7. Terminal care including nursing services, hospice, or general hospital wards
8. Preventive measures for health care professionals
9. Post-exposure prophylaxis in cases of occupational exposure

Note: Guideline developers considered several other prevention and treatment options. For a list of these, see the "Major Recommendations" field below.

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests

- Incidence of human immunodeficiency virus (HIV) infection
- Rate of transmission
- Rate of occupational exposure
- Incidence of opportunistic infections
- Patient compliance with medication regimen
- Morbidity and mortality due to HIV infection

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
 Hand-searches of Published Literature (Secondary Sources)
 Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence reviewed was collected from the Cochrane database of systematic reviews and the Database of Abstracts of Reviews of Effectiveness (DARE). In addition, the Cochrane Library and medical journals were searched specifically for original publications.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

A. Quality of Evidence: High

Further research is very unlikely to change confidence in the estimate of effect

- Several high-quality studies with consistent results
- In special cases: one large, high-quality multi-centre trial

B. Quality of Evidence: Moderate

Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.

- One high-quality study
- Several studies with some limitations

C. **Quality of Evidence: Low**

Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.

- One or more studies with severe limitations

D. **Quality of Evidence: Very Low**

Any estimate of effect is very uncertain.

- Expert opinion
- No direct research evidence
- One or more studies with very severe limitations

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence [A-D] supporting the recommendations are defined at the end of the "Major Recommendations" field.

Basic Rules

- Identification of the human immunodeficiency virus (HIV)-infected persons is most essential.
- Suspect HIV infection on clinical grounds
 - In patients exposed to HIV infection in unprotected sex or via injections
 - In patients with a history of high-risk behaviour and who present with symptoms suggesting primary HIV infection
 - In patients with unexplained immunosuppression and in young individuals with weight loss, dementia or oesophageal candidiasis, thrombocytopenia, or anaemia without a clear cause
- Antibodies will become positive in 1 to 4 months after contracting the infection. To exclude the possibility of HIV infection, the development of antibodies should be followed up until four months have elapsed. The primary symptoms may become manifest 2 to 6 weeks after the transmission.
- There is no cure for HIV infection, but a combination therapy (highly active antiretroviral therapy [HAART]) has greatly improved the patients' outlook (Rutherford, Sangani, & Kennedy, 2003) [**A**].

Epidemiology

- According to the World Health Organization (WHO), in 2004 an estimated 5 million new infections with HIV were diagnosed worldwide, a total of 3 million people died of HIV/acquired immunodeficiency syndrome (AIDS)-related causes, and there were 40 million people living with HIV/AIDS.
- In Western Europe, new infections are mainly related to sex tourism, prostitution, and use of intravenous drugs.

Natural Course of HIV Infection

Primary Infection

- Primary HIV infection develops in 30% to 50% of infected patients, 2 to 6 weeks after contracting the virus.
- The symptoms may include fever, tiredness, sore throat, headache, diarrhoea, myalgia, arthralgia, and occasionally enlarged lymph nodes as well as an eruption of small papules on the body. Primary infection often resembles mononucleosis. The symptoms resolve within a month. Diagnosis is made difficult by the fact that during primary infection over 50% of the patients will be HIV antibody negative. The HIV antigen test and polymerase chain reaction (PCR) assay become positive at an earlier stage. A positive PCR assay warrants confirmation with other test methods at a later stage (Owens et al., 1996) [**C**].

Asymptomatic Phase

- Lasts for several years, in some cases over 10 years

- A high viral load will hasten the disease progression.

Symptomatic HIV Infection

- CD4 cell count has often decreased to below $0.35 \times 10^9/L$.
- An increasing viral load is often predictive of symptom emergence.
- Symptoms are non-specific, such as weight loss, fever, and persistent diarrhoea.
- Herpes zoster (shingles), oropharyngeal candidiasis, and seborrhoeic eczema (see Picture 1 in the original guideline document) are also indicative of reduced immune response.

AIDS

- AIDS is defined as an HIV infection with at least one of the officially listed opportunistic diseases.
- The introduction of HAART has significantly reduced the occurrence of opportunistic diseases.
- The most common opportunistic diseases in Western Europe are:
 - Fungal oesophagitis or stomatitis
 - Infections caused by atypical mycobacteria (*Mycobacterium avium-intracellulare*)
 - *Pneumocystis jirovecii* pneumonia
 - Kaposi's sarcoma
- Tuberculosis is common in the rest of the world.

Indications for an HIV Test

- An HIV test may be indicated particularly in the following clinical conditions:
 - There is a history of high-risk behaviour: unprotected sex with occasional partners or with prostitutes, or use of intravenous drugs
 - Sexually transmitted diseases
 - Fever, diarrhoea, weight loss, or dementia of unknown origin
 - Unexplained thrombocytopenia
 - Tuberculosis in a young or middle-aged person
 - Pneumonia caused by *Pneumocystis jirovecii* (opportunistic pneumonia typically presenting with slow onset, dyspnoea on exertion, hypoxaemia, and mild or moderate fever)
 - Widespread oral candidiasis associated with dysphagia or pain on swallowing (oesophageal candidiasis)
 - Kaposi's sarcoma (wine-red or violet spots or tumours in the palate, gums, or skin)
- HIV serology should always be tested on the patient's request.
- The patient should be asked for consent before HIV testing. If the patient declines the test, the problems and possible harm caused by the delayed diagnosis, both for the patient himself/herself, the treating personnel (extra investigations and prolonged treatment time), and other people (infection risk) should be further explored with the patient.
- Pregnant women are offered voluntary screening at maternity clinics.

Diagnosis

- HIV antibody test. A positive sample is retested; if it remains positive the laboratory will request a further sample before submitting a result.
- The test will become positive 2 to 4 weeks after symptom onset or 1 to 4 months after contracting the virus.
- HIV nucleic acid test should be considered when strong suspicion of the infection exists in a patient with primary symptoms and if urgent diagnosis is required and the antibody test is negative.

Investigations and Patient Education in Primary Care

- Adequate time must be allocated for breaking the news of a positive test result. The patient should also be given contact details of how to obtain more information or moral support (AIDS help lines are available 24 hours a day).
- If the result is negative the patient should be given advice regarding high-risk behaviour and the possible need of a repeat test.
- Any unit carrying out HIV testing should be able to provide a patient whose HIV test result is positive with general information regarding the mode of HIV transmission, course of the disease, and the treatment choices available. The unit should also be prepared to answer any questions relating to daily hygiene needs, etc. (Wolitski et al., 1997) [B].
- The disease staging and the assessment of an individual patient's prognosis, as well as the decision on specific drug therapies, are carried out by a specialist team.
- As soon as a positive test result is obtained, every effort should be made to identify and inform the patient's past contacts, who should be encouraged to agree to be tested.
- An official notification of an infectious disease should be made.
- If the patient is an intravenous drug user, a hepatitis B vaccination programme is commenced unless the patient has had the disease or has already been vaccinated. Also the hepatitis C virus (HCV) antibodies should be investigated.
- The follow-up of the patient is usually undertaken by an infectious disease team.

Treatment

- See the National Guideline Clearinghouse (NGC) summary of the Centers for Disease Control and Prevention (CDC) guideline: [Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents](#).

Specific Treatment with HIV Drugs

- Treatment of an HIV infection requires specialist skills, and the prescription and implementation of drug therapies should be undertaken only by those experienced in their use.
- The development of HIV drugs has significantly improved the prognosis of an HIV infection. No cure exists, but it may be possible to add several tens of years to the life expectancy of an HIV positive patient. Quality of life has also improved significantly as has the patients' ability to continue in working life.
- Indications for starting drug therapy for an HIV infection are:
 - Symptomatic disease (particularly if AIDS is diagnosed)
 - Asymptomatic disease, if CD4 cell count falls below $0.35 \times 10^9/L$

- An HIV positive pregnant mother (to prevent vertical transmission) (Brocklehurst, 2002) [A]
- The treatment is carried out with the combination of at least three antiviral drugs (HAART) (Rutherford, Sangani, & Kennedy, 2003) [A].
- During effective drug treatment, the viral load in plasma is below detection threshold (40 copies/mL) and due to successful treatment, the CD4 count increases and the risk of complications decreases.
- Once antiviral drug therapy has been started, its uninterrupted continuation is of vital importance.
 - Development of drug resistance and loss of efficacy may follow irregular adherence to therapy.
 - The treatment must not be interrupted without prior consultation with the treating physician.
 - HIV drugs interact with several other drugs. There is potential for too high or too low concentrations of either drug. Specialist consultation should always be sought in unclear cases.
- Patient compliance is the most important factor in successful drug therapy for HIV infection.
 - Adverse effects are common, particularly in the beginning.
 - To facilitate dosing at the same time every day may involve some lifestyle changes.
 - To maintain a long-term treatment response, at least 95% of the drug doses should be taken at the specified time.
- The risk of foetal transmission is below 1% provided that the maternal infection is detected in time and that HAART-treatment decreases the viral load in maternal plasma below detection threshold before delivery.

HIV and the General Practitioner

- The asymptomatic phase lasts for a long time, and the correct timing of the specific antiviral drugs effectively reduces the occurrence of opportunistic diseases. These patients will visit their general practitioner (GP) more often than before with common infections, skin or dental problems, or with problems totally unrelated to their positive HIV status.
 - When an HIV positive patient presents with a febrile illness, the treating specialist unit should be consulted over the telephone in all unclear cases, particularly if antiretroviral medication has been introduced.
 - Abnormal headache, paralysis, impaired consciousness, or visual disturbances in an HIV positive patient always warrant an immediate referral to specialist care for further investigations.
- HIV is not curable with current drug therapies, and the introduction of terminal care may have to be broached at some stage. The options include home nursing services, hospices, or general hospital wards. The situation should be anticipated in good time to allow the appropriate staff time to undertake any additional training.

The Working Capacity of HIV Carriers

- During the asymptomatic phase, the working capacity of the patient usually remains normal.

- The decreased working capacity during primary infection is transient. AIDS might cause permanent loss of working capacity or it may be restored by antiviral treatment.
- Infection risk does not usually contribute towards the patient's inability to work.

Guidelines for Health Care Professionals

- When exposure to blood is a possibility, gloves and a facial shield protecting also the eyes should be worn.
- Gloves should be worn when taking blood samples, but there is no need to wear a facial shield (if vacuum tubes are used).
- Particular attention should be paid to following recommended procedures in order to avoid needle stick injuries.

Post-Exposure Prophylaxis in an Occupational Setting

- The risk of infection is very small. After verified HIV exposures associated with needle stick injuries, the risk has been around 0.1 percent.
- In percutaneous exposure, where the source patient is known to be HIV positive, prophylaxis is recommended with a combination of three drugs for four weeks. The treatment should be started within two hours of the exposure, but it has an effect even when started within two days. Post-exposure prophylaxis has been found to be effective (Talbot, 2004) [**B**] but should be reserved for cases where the potential for infection transmission exists because of the potentially dangerous adverse effects. Prophylaxis after mucous membrane exposure is discretionary. An infectious disease physician should be consulted in uncertain cases and in order to obtain assistance in risk assessment.
- The decision about initiating post-exposure prophylaxis must be made by a physician with HIV experience. Health care staff must have access to post-exposure prophylaxis 24 hours a day.
- An HIV antibody test should be taken without delay and again after 1, 3, and 6 months.
- If antiviral medication was prescribed for prophylaxis, antibody testing may be continued for even longer.
- Official notification must always be made of a needle stick injury.
- During the follow-up period, a condom must be used during sexual intercourse (Weller & Davis, 2002) [**B**].

Related Resources

Refer to the original guideline document for related evidence, including Cochrane reviews and other evidence summaries.

Definitions:

Levels of Evidence

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- In special cases: one large, high-quality multi-centre trial

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- One high-quality study
- Several studies with some limitations

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- One or more studies with severe limitations

D. Quality of Evidence: Very Low

Any estimate of effect is very uncertain.

- Expert opinion
- No direct research evidence
- One or more studies with very severe limitations

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Concise summaries of scientific evidence attached to the individual guidelines are the unique feature of the Evidence-Based Medicine Guidelines. The evidence summaries allow the clinician to judge how well-founded the treatment recommendations are. The type of supporting evidence is identified and graded for select recommendations (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate diagnosis, treatment, and management of human immunodeficiency virus (HIV) infection
- The development of HIV drugs has significantly improved the prognosis of an HIV infection. No cure exists, but it may be possible to add several tens of years to the life expectancy of an HIV positive patient. Quality of life has also improved significantly as has the patients' ability to continue in working life.

POTENTIAL HARMS

- Adverse effects of HIV drugs are common.
- HIV drugs interact with several other drugs. There is potential for too high or too low concentrations of either drug.
- Post-exposure prophylaxis has been found to be effective, but should be reserved for cases where the potential for infection transmission exists because of the potentially dangerous adverse effects.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Finnish Medical Society Duodecim. HIV infection. In: EBM Guidelines. Evidence-Based Medicine [Internet]. Helsinki, Finland: Wiley Interscience. John Wiley & Sons; 2007 Mar 16 [Various].

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Aug 12 (revised 2007 Mar 16)

GUIDELINE DEVELOPER(S)

Finnish Medical Society Duodecim - Professional Association

SOURCE(S) OF FUNDING

Finnish Medical Society Duodecim

GUIDELINE COMMITTEE

Editorial Team of EBM Guidelines

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Janne Laine; Janne Mikkola

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Finnish Medical Society Duodecim. HIV infection. In: EBM Guidelines. Evidence-Based Medicine [Internet]. Helsinki, Finland: Wiley Interscience. John Wiley & Sons; 2006 Mar 24 [Various].

GUIDELINE AVAILABILITY

This guideline is included in a CD-ROM titled "EBM Guidelines. Evidence-Based Medicine" available from Duodecim Medical Publications, Ltd, PO Box 713, 00101 Helsinki, Finland; e-mail: info@ebm-guidelines.com; Web site: www.ebm-guidelines.com.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on August 30, 2005. This summary was updated by ECRI on October 27, 2005, May 25, 2006, and December 31, 2007.

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